REMARKS

1. Applicant confirms election of Group I (claims 75-107, and including claim 123) and the election for search purposes only of a polypeptides comprising a sequence identical to or related to SEQ ID NO: 3 in our reply filed on June 9, 2006.

2.-4. Applicant affirms that claims 75, 84-91, 93-106, and 123 are currently pending. Claim 75 is amended to replace the term "detecting" with "determining" in the preamble. This amendment is supported throughout the specification, for example at lines 27-28 on page 25. Claim 75 is further amended by replacing "is indicative of" with "indicates that the subject is likely to have"; this amendment is likewise supported in the specification at, for example, lines 21-23 of page 5 and lines 7-12 of page 8. Claims 84, 85, and 90 are amended to correct form; claims 101 and 104-106 are amended to include proper antecedent basis. New claim 124 is drawn to the elected group of claims and is supported throughout the specification. Thus the claim amendments introduce no new matter.

Information Disclosure Statement

5. Applicant notes with appreciation that the Examiner has considered the Information Disclosure Statements filed to date in this application.

Election/Restrictions

6. As noted in Point 1 above, Applicant confirms the election made in the response filed on June 9, 2006.

Priority

7. The Examiner alleges that claims 75, 84-91, 93, and 95-106 do not properly benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents cited, since these claims stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure. Applicant respectfully disagrees. The applications as filed are

fully compliant with the requirements of the first paragraph of 35 U.S.C. § 112 as will be evident from the discussion below.

The Examiner further argues that with particular regard to claims 86 and 87, even if issues related to the insufficiency of the disclosure under 35 U.S.C. § 112, first paragraph, were resolved, the prior filed applications allegedly do not describe the practice of the claimed invention of claims 86 and 87. Accordingly, the Examiner has deemed the effective filing date of claims 75, 84-91, 93, and 95-106 to be the filing date of the instant application: August 26, 2003.

Applicant traverses. Both the parent and the instant applications satisfy the requirements set forth under 35 U.S.C. § 112, first paragraph, for claims 75, 84-91, 93, and 95-106 for at least the reasons outlined below. With regard to claims 86 and 87, the parent applications (Serial Nos. 10/274,177 and 10/299,345) both disclose using a biological sample such as a stool sample. U.S. Application No. 10/274,177 describes detecting markers in stool samples (see, for example, paragraphs 0004, 0014, 0112, 0114, 0144, 0150, and claim 17). U.S. Application No. 10/299,345 similarly describes using stool samples.

One of ordinary skill in the art would readily appreciate that a stool sample includes both excreted stool and stool removed from within the colon (see page 9, line 18, for example, of the instant application). Furthermore, excreted stool is an embodiment of a biological sample derived from the inner wall and/or lumen of the intestinal tract. Accordingly, Applicant respectfully requests the Examiner reconsider the appropriateness of the instant application's priority claim.

Objections to Drawings and Specification

8.-10. The Examiner has objected to Figures 34, 35, and 41 because the figures depict nucleotide or amino acid sequences which are not identified by sequence identification numbers. Sequence identification numbers for sequences appearing in the figures may be provided either in the figures or in the brief description of the figures. Accordingly, Applicant has amended the brief description of the figures to include sequence identification numbers for the sequences depicted in Figures 34, 35, and 41 (Applicant notes that Figure 41 includes a sequence identification number at the end of the sequence; this sequence identification number is now also included in the figure legend to Figure 41). These amendments introduce no new matter.

Applicant has also submitted replacement paper and computer-readable sequence listings and requests that these replacement sequence listings be entered into the specification. The content of the paper and computer-readable sequence listings are the same and are based on subject matter originally filed in the instant application and therefore introduce no new matter.

The Examiner has objected to the specification for the use of improperly demarcated trademarks. Accordingly, Applicant has amended the specification to include where appropriate trademark designations.

Claims Objections

11.-14. Claims 75, 84-91, and 95-106 are objected to as these claims include in the alternative non-elected subject matter. Applicant notes that the Examiner has indicated that since these claims may be rejoined no action is necessary at this point.

In accordance with the Examiner's suggestion, the preamble of claim 75 is amended to recite "a colon neoplasm" rather than "a colon neoplasia". Applicant interprets the terms "neoplasm" and "neoplasia" to be synonymous and thus this amendment does not change the scope of the claim.

The Examiner has objected to the dependency of claim 85 from claim 84, stating that claim 85 does not limit the scope of the claimed invention of claim 84. Claim 84 is drawn to a biological sample that is either a blood sample or a fraction derived from blood. Claim 85 requires that the biological sample be selected from among whole blood and two fractions derived from blood: plasma and serum. In response to the Examiner's objection, Applicant has amended the claims such that claim 85 recites embodiments of claim 84. While the amendments to claims 84 and 85 render the dependency appropriate, these claim amendments together do not alter the scope of the claimed invention.

Finally, claim 90 is amended to correct form as the Examiner has required.

Claims Rejections – 35 U.S.C. § 112, second paragraph

15.-16. The Examiner has rejected claims 75, 84-91, 93, and 95-106 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In brief, the Examiner states that the intended use preamble (a method for determining whether a subject is likely to a colon neoplasm) and a recitation in the claimed method (wherein the presence of a polypeptide is indicative of a colon neoplasm) lack agreement. While not acquiescing to the propriety of this rejection, solely in an effort to expedite prosecution, claim 75 is amended to recite in the body of the claim "wherein the presence of said at least one polypeptide indicates that the subject is likely to have a colon neoplasm".

The Examiner has rejected claim 99 as indefinite for the recitation "the subject's historical baseline". The Examiner contends that the specification does not describe with any particularity what value(s) represent the subject's historical baseline nor how such value(s) are measured or determined. This recitation refers to the subject's historical baseline level of a polypeptide measured in a subject's sample, as is clear from the claims and the specification (see, for example, lines 20-27, page 3 of the specification). Applicant traverses on the grounds that absolute values are not relevant as this measurement is used in a comparison (as the baseline, or the value or values that can serve as a comparison or control) for similar measurements[1]. This baseline level may be measured or determined in the same way as a current measurement is determined (e.g., by Western blot, immunoprecipitation, ELISA, etc., see section 5. Methods for Detecting Molecular Markers in a Patient, pages 45-49 of the specification, for example). All that is required is that it is a historical measurement—i.e., that it was made at some previous point in time. Thus Applicant contends that the meaning of "the subject's historical baseline" is clearly evident from the plain meaning of the claim terms and is described in the teachings of the specification.

In response to the Examiner's rejections of claims 100 and 103 as allegedly vague and/or indefinite, Applicant has amended claim 75 as stated above, thus rendering these rejections moot.

Claims Rejections – 35 U.S.C. § 112, first paragraph, written description

[1] Similar measurements refer to measurements determined using the same or similar assay or protocol and that are therefore in the same or comparable units.

17.-18. The Examiner has rejected claims 75, 84-91, 93, and 95-106 under 35 U.S.C. § 112, first paragraph, contending that the claims do not comply with the written description requirement. The Examiner states that the claims are directed to a genus of secreted polypeptides having an amino acid sequence of SEQ ID NO: 3 and contends that an amino acid sequence of any particular amino acid sequence is understood to be *any two* or more contiguous amino acids of the particular amino acid sequence. The Examiner argues that support for this interpretation is found in the specification at paragraph 0073.

Solely in an effort to expedite prosecution and not in acquiescence to this rejection the claims have been amended to obviate this ground of the rejection.

The Examiner further contends, that the specification, in providing SEQ ID NO: 3, provides only one species of the genus of polypeptides and does not describe "with any degree of particularity, for example, any other polypeptides having amino acid sequences that are at least substantially identical (e.g., 95%) to the amino acid sequence of SEQ ID NO: 3" (pages 12-13 of the Office Action). The Examiner also states "there is no disclosure that reasonably suggests that the single discloses [sic] species of the genus to which the claims are directed should be regarded as representative of the genus, as a whole, as, for example, the specification fails to describe any one particularly (i.e., substantial) structural feature that is shared by the polypeptide of SEQ ID NO: 3 and other members of the genus, which correlates with any one particularly identifying functional feature, which is also shared by the polypeptide of SEQ ID NO: 3 and at least most other members of the genus".

Applicant respectfully disagrees. First, the specification teaches that ColoUp nucleic acids and polypeptides refer to:

> . . . nucleic acid encoding a ColoUp protein or a ColoUp protein itself, as well as distinguishable fragments of such nucleic acids and proteins, longer nucleic acids and polypeptides that comprise distinguishable fragments or full length nucleic acids or polypeptides, and variants thereof. Variants include polypeptides that are at least 90% identical to the relevant human ColoUp SEQ ID Nos. referred to in the application, and nucleic acids encoding such variant polypeptides. In addition, variants include different post-translational modifications, such as glycosylations, methylations, etc. Particularly preferred variants include any naturally occurring variants, such as allelic differences, mutations that occur in a neoplasia and secreted or processed forms. The terms "variants" and "fragments" are overlapping.

See page 19 lines 14-24. The specification provides the amino acid sequence of the full-length secreted and processed forms of the ColoUp2 polypeptide and fragments thereof. The specification also discloses specific polymorphisms that have been observed in the ColoUp2 nucleic acid sequences; for example, at nucleotide 113 GCC→ ACC (Ala-Thr); nucleotide 480 GAA→ GGA (Glu-Gly); and at nucleotide 2220 CAG→ CGG (Gln-Arg). Contrary to the Examiner's assertions the specification also describes various structural features of this polypeptide; for example the specification teaches that the sequence of ColoUp2 protein is similar to that of alpha 3 type VI collagen, isoform 2 precursor and comprises domains such as a von Willebrand factor type A domain and an EGF-like domain (page 34 lines 4-18 of the specification, for example).

The Examiner also argues that "although the polypeptide of SEQ ID NO: 3 may be differentially expressed in colon cancer, the skilled artisan cannot predict which of the many other polypeptides to which the claims are directed are also over- or under-expressed in colon cancer" (page 14 of the Office Action). The Examiner contends that the skilled artisan cannot predict whether a particular member of a family is associated with the etiology or pathology of a disease solely on the basis that another member of the family has shown to be. The Examiner cites De Plaen et al. (Immunogenetics 1994 (40): 360-369, cited by Applicant), who describe 12 *MAGE* genes and measure their expression in tumor and healthy tissue samples. De Plaen et al. demonstrate that 6 of the 12 *MAGE* genes (*MAGE-1, 2, 3, 4, 6,* and *12*) exhibit significant expression in a number of different tumor types, whereas 5 of the *MAGE* genes (*MAGE-5, 8, 9, 10,* and *11*) are weakly expressed. However, while these genes are from the same family, these genes do not necessarily represent "variants" of each other as the term "variants" is used to describe ColoUp2 polypeptides. For example, the percentage identities for the coding sequence of *MAGE-1* with the coding sequences of the other *MAGE* genes varies from between 64% and 85%, and the putative MAGE proteins *2-6* and *8-12* are 57% to 77% percent identical with *MAGE-1* (pages 364-365 of De Plaen et al.[2]). Accordingly, these genes encode proteins that, although they may have similar structural features, are indeed different and distinct proteins under the control of different regulatory sequences (see abstract: "...the promoters and first exons of the 12 *MAGE* genes show

[2] Applicant notes that the *MAGE-12* gene sequence is 90% identical to *MAGE-2* but lacks an additional exon, and that the gene sequence of *MAGE-6* is 99% identical to *MAGE-3* (page 364); all four of these *MAGE* genes were found to be significantly expressed in tumor samples.

considerable variability..."). Applicant contends that regardless of whether family members of the protein family to which ColoUp2 belongs are up- or down-regulated in colon neoplasia, the application clearly teaches that the ColoUp2 polypeptides, including secreted and processed forms of SEQ ID NO: 3, are up-regulated in colon neoplasia. Applicant contends that the claims are directed to polypeptides that satisfy the description of a ColoUp2 polypeptide presented above and therefore excludes polypeptides that are, for example, 60% identical to SEQ ID NO: 3 but that may be in the same family as ColoUp2.

The Examiner additionally has rejected claims 98 and 99 for the recitations "a predetermined standard" and "the subject's historical baseline", respectively. The Examiner contends that the value of the predetermined standard must be known to practice the claimed invention and has not been particularly described. Similarly, according to the Examiner, the instant disclosure (allegedly) does not sufficiently describe the value that constitutes a subject's historical baseline nor how such value(s) are measured or determined.

Applicant traverses. The subject matter encompassed by the claim phrases "predetermined standard" and "the subject's historical baseline" are apparent to the skilled artisan by the plain meaning of the claim terms. The terms "standard" and "baseline" both refer to a value or values that serve as a basis for comparison or as a control. To paraphrase the phrase "predetermined standard", for example, a predetermined standard amount of a ColoUp2 polypeptide is any "known amount" (e.g., page 9 line 31) of a ColoUp2 polypeptide that has been measured or determined in the past (i.e., that is "predetermined"). Similarly, the specification refers to a subject's historical baseline also as a subject's "past" baseline (e.g., 29-30, page 3). The values of both a predetermined standard level and a subject's historical baseline level of a ColoUp2 polypeptide may be measured or determined by any one of a variety of methods (see, for example, section 5. Methods for Detecting Molecular Markers in a Patient, pages 45-49 of the specification). It is evident to the skilled artisan that, in order to "compare" two measurements (e.g., (1) a measurement(s) used to determine a standard level and/or a subject's baseline level and (2) a measurement according to the method of claim 75) the measurements must be "comparable", which, in most instances, is accomplished by using the same or similar methods to obtain the two measurements (in this case, ColoUp2 levels); it is readily apparent to the skilled artisan that in order to serve as a baseline or standard for comparison (e.g. as a control), such a baseline or standard

value must be compatible (i.e., comparable) with the measurement for which the standard or baseline is used as the basis for comparison. The absolute values are not necessarily relevant as these measurements are used to determine a relative difference or change between two measurements (e.g., see page 6, lines 20-25). All that is required is that a measurement(s) that serves as the baseline or standard is made prior to the current measurement. Thus the predetermined standard level or baseline level is "a known amount" (page 9 line 31). To practice the claimed invention, therefore, the skilled artisan requires a method for detecting ColoUp2, and the specification provides sufficient disclosure for such methods of detection.

Accordingly, in light of at least the forgoing remarks, Applicant contends that the instant application satisfies the written description requirement for polypeptides having an amino acid sequence of SEQ ID NO: 3; the specification describes a representative number of species as well as structural features of such polypeptides. In addition, reference to baseline or standard amounts of a ColoUp2 polypeptide encompasses subject matter that is readily apparent by the plain meaning of the claim terms. Applicant respectfully requests the Examiner reconsider and withdraw the written description rejection.

Claims Rejections – 35 U.S.C. § 112, first paragraph, enablement

19. The Examiner has rejected claims 75, 84-91, 93, and 95-106 under 35 U.S.C. § 112, first paragraph, contending the specification does not provide sufficient enabling disclosure for the claimed invention. The Examiner states that although the specification is enabling for a method for detecting colon neoplasia in a subject, the specification does not reasonably provide enablement for using such a method for determining whether a subject is likely to have colon neoplasia (Office Action, page 17). The Examiner contends that the claims are directed to a genus of polypeptides that differ both structurally and functionally as the Examiner has defined "variants" of the polypeptide of SEQ ID NO: 3 as polypeptides having an amino acid sequence comprising at least two contiguous amino acids of the amino acid sequence set forth as SEQ ID NO: 3. Accordingly the Examiner asserts that the specification does not describe any such "variant" as described above (a polypeptide having an amino acid sequence comprising at least two contiguous amino acids of the amino acid sequence of SEQ ID NO: 3) which is associated with colon neoplasia (Office Action

pages 18-19). Therefore, the Examiner concludes, "any success in practicing of the claimed invention by determining the presence of any polypeptide other than the polypeptide of SEQ ID NO: 3 is largely unpredictable" (Office Action page 19). The Examiner accordingly contends that the amount of guidance and exemplification provided in the specification would not be sufficient to enable the skilled artisan to use the claimed invention at the time the application was filed without undue experimentation.

Applicant respectfully submits that the claims amendments obviate this ground of the rejection.

The Examiner has also rejected claim 98 contending that since the value of the predetermined standard must be known to practice the claimed invention, the invention of claim 98 cannot be practiced as this value, according to the Examiner, has not been particularly described (page 19 of the Office Action). Applicant traverses. The meaning of this claim recitation, as argued above, is readily apparent to the skilled artisan by the plain meaning of the claim terms. Moreover, while the absolute value of the predetermined standard level of a ColoUp2 polypeptide is not necessarily relevant to the claimed invention, the specification teaches how to practice the method of claim 98. See, for example, lines 21-30 on page 3, where the specification teaches detecting in a subject's biological sample an amount of a ColoUp2 polypeptide and comparing the amount of the polypeptide with a predetermined standard, wherein detection of a level of ColoUp2 in the subject's sample that is greater than the level of the predetermined standard is indicative of colon neoplasia. A predetermined standard may be any known amount of a ColoUp2 polypeptide and may be represented by any unit of measure that is comparable to the measurement of detected ColoUp2 in the subject's sample. For example, any of the levels of ColoUp2 in Figure 21A could be used as a predetermined standard if a subject's sample were also measured by microarray. Determining a standard amount of ColoUp2 polypeptide according to the claimed invention does not represent undue or unreasonable experimentation as using standards for controls or as baselines for comparisons is commonly practiced. Accordingly, Applicant contends that the specification fully enables the method of claim 98.

The Examiner has similarly rejected claim 99, arguing that the specification does not provide sufficient written disclosure for the value of a "subject's historical baseline" nor how such values are measured or determined and thus concludes that the method of claim 99 cannot be practiced. Applicant traverses. The specification teaches how to detect levels of ColoUp2 (see, for

example, section 5. Methods for Detecting Molecular Markers in a Patient, pages 45-49 of the specification) and how to use such levels as a subject's historical baseline for comparison. See, for example, lines 21-30 on page 3, where the specification teaches detecting in a subject's biological sample an amount of a ColoUp2 polypeptide and comparing the amount of the polypeptide with the subject's historical baseline, wherein detection of a level of ColoUp2 in the subject's sample "that is increased from a subject's *past* baseline is indicative of a condition such as colon neoplasia" (lines 29-30, page 3, *emphasis added*). As stated above in response to the written description rejection, the actual absolute value of a subject's historical baseline is not required to describe or provide enablement for the claimed invention, as this value is case dependent and may vary from subject to subject and also depends on the method of detection. The specification, nonetheless, teaches how to obtain this value and how this value is to be used in the claimed invention. Accordingly, the specification fully enables the method of claim 99, and Applicant requests the Examiner reconsider and withdraw this rejection.

Claims Rejections – 35 U.S.C. § 102

20.-21. The Examiner has rejected claims 75, 84, 85, 89-91, 93, 95-97, and 100-106 under 35 U.S.C. 102(a) as allegedly being anticipated by WO 2002/068677 A1 (*Mack et al.*, of record, cited by Applicant). The Examiner contends that *Mack et al.* teaches a secreted polypeptide comprising an amino acid sequence of SEQ ID NO: 3 and teaches detecting this polypeptide in a biological sample from a subject with colon cancer or precancerous conditions (pages 20-21 of the Office Action).

Applicant traverses. In order to anticipate the claimed invention, a reference must disclose all of the limitations of the claimed subject matter. *Mack et al.* does not disclose SEQ ID No: 3. The Examiner cites SEQ ID NO: 23 of *Mack et al.*, but this sequence differs from SEQ ID NO: 3 of the instant application at the C-terminal end, where amino acids FLRRP of SEQ ID NO: 3 are replaced with a 30 amino acid sequence (amino acids 751-780 of SEQ ID NO: 23). Accordingly, *Mack et al.* fails to teach each and every limitation of the claimed invention and thus fails to anticipate the claimed invention.

Moreover, although *Mack et al.* lists genes that are either upregulated or downregulated in metastatic colon cancer (liver metastasis) compared to normal or non-metastatic colon samples, *Mack et al.* does not teach which genes (e.g., up- or down-regulated genes) to detect in order to

determine whether a subject is likely to have colon neoplasia. Tables 1-26 of *Mack et al.* list both up- and down-regulated genes in colon cancer-derived liver metastases samples. Page 25 of *Mack et al.* states "In a preferred embodiment, metastatic colorectal cancer sequences are those that are *up-regulated* in metastatic colorectal cancer..." and page 26 states "In another preferred embodiment, metastatic colorectal cancer sequences are those that are *down-regulated* in the metastatic colorectal cancer..." (*emphasis added*). Further, on pages 7-8, the disclosure recites "Alteration of gene expression for a gene from Tables 1-26 may be *more likely or less likely* to indicate that the subject will progress to metastatic disease....Alteration of gene expression for a gene from Tables 1-26 *may or may not* indicate that the subject is more likely to progress to cancer or to metastatic disease" (*emphasis added*).

Thus, *Mack et al.* fails to specify which genes (up- or down-regulated genes), or which of the up- or down-regulated genes in mets, indicate that a patient is likely to have colon adenoma or colon cancer. Specifically, *Mack et al.* fails to teach any correlation between a specific sequence of Tables 1-26 (e.g., SEQ ID NO: 23) and a subject's likelihood of having colon neoplasia. Accordingly *Mack et al.* fails to teach that detection of SEQ ID NO: 23 is indicative that a subject is more likely (rather than less likely) to have colon neoplasia. The instant application, however, teaches that the presence of SEQ ID NO: 3 or a secreted or processed form thereof indicates that a subject is likely to have colon neoplasia. As *Mack et al.* fails to teach that the presence of, or increased expression of, SEQ ID NO: 23 correlates with an increased likelihood of having a colon neoplasm, and as SEQ ID NO: 23 does not anticipate SEQ ID NO: 3, *Mack et al.* fails to anticipate the claimed invention.

The Examiner has also rejected 75, 84, 85, 89-91, 93, 95-97, 100-103, 105, and 106 under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2003/0077568 A1 (*Gish et al.*). The Examiner contends that *Gish et al.* teaches detecting colon cancer in a subject by determining the presence of a polypeptide depicted as SEQ ID NO: 2 in a biological sample and that SEQ ID NO: 2 of *Gish et al.* is a polypeptide comprising an amino acid sequence of SEQ ID NO: 3 of the instant application.

Applicant traverses. SEQ ID NO: 2 of *Gish et al.*, like SEQ ID NO: 23 of *Mack et al.*, differs from SEQ ID NO: 3 of the instant application and thus fails to anticipate the claimed invention. Furthermore, *Gish et al.* fails to teach whether up- or down-regulation of SEQ ID NO: 2

indicates whether a subject is likely to have colon cancer or to progress to metastatic disease. For example, paragraph [0025] teaches

> "Treatment, monitoring, detection or modulation of colorectal cancer" includes treatment, monitoring, detection, or modulation of colorectal disease in those patients who have colorectal disease (Dukes stage A , B, C or D) in which gene expression from a gene in Table 1 or 2, *is increased or decreased*, indicating that the subject is more likely to progress to metastatic disease than a patient who does not have an increase or decrease in gene expression of a gene in Table 1 or 2. *emphasis added*

In addition, paragraphs [0039] and [0040] refer to colorectal cancer sequences as sequences that can be either up- or down-regulated in colorectal cancer. The claimed invention of the present application, however, is directed to a method wherein the presence of ColoUp2 indicates that a subject is likely to have a colon neoplasm, and when comparing to a baseline or standard level of ColoUp2 polypeptide, the instant specification teaches the correlative relationship between levels of ColoUp2 and the likelihood of having colon neoplasia (see, for example, lines 21-30 on page 3 of the instant application). Accordingly, *Gish et al.* fails to anticipate the claimed invention.

The claims have been amended solely to expedite prosecution and Applicants reserve the right to prosecute subject matter of claims as originally filed in the present or future applications.

In view of at least the forgoing remarks and the claim amendments, Applicant requests reconsideration and withdrawal of rejections under 102(a) and 102(e).

CONCLUSION

In view of the amendments and at least the forgoing remarks, Applicant believes the pending application is in condition for allowance and requests the Examiner reconsider the pending claims. If any fees in addition to the fee supplied with the Request for an Extension of Time are due, please charge our Deposit Account No. 18-1945, under Order No. CWRU-P03-003 from which the undersigned is authorized to draw.

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Respectfully submitted,

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